

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

**IN RE NATIONAL PRESCRIPTION
OPIATE LITIGATION**

This document relates to:

*County of Summit, Ohio, et al. v. Purdue
Pharma L.P., et al.*

Case No. 18-OP-45090 (N.D. Ohio)

MDL No. 2804

Case No. 17-md-2804

Judge Dan Aaron Polster

DECLARATION OF KRISTA TONGRING

I, Krista Tongring, declare as follows:

1. I am over 21 years of age and I am competent to make this declaration. I have personal knowledge of the facts set forth below and, if called as a witness, I would and could testify to the same.

2. I am an attorney in good standing and have been continually licensed to practice law in the State of New Jersey since 1996.

3. The expert report I prepared in the above-captioned case was served on all parties on May 10, 2019. A copy of my expert report, which I signed, is included as Exhibit A.

4. I am adopting my expert report (Ex. A) as my sworn statement in the above-captioned case, and, pursuant to 28 U.S.C. § 1746, I hereby declare under penalty of perjury under the laws of the United States of America that the contents of that report are true and correct.

5. Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed on June 20, 2019.

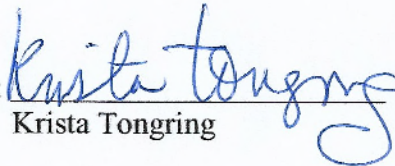
By: 
Krista Tongring

EXHIBIT A

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE NATIONAL PRESCRIPTION OPIATE
LITIGATION

MDL No. 2804

Case No. 1:17-MD-2804

Judge Dan Aaron Polster

This document relates to:

*Track 1 Cases – Cuyahoga County and Summit
County*

Expert Report of Krista Tongring

May 10, 2019

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

I. Introduction and Summary of Opinions

- A. I have been engaged by Walmart Inc. (Walmart) in connection with the following two cases: *The County of Cuyahoga, Ohio, v. Purdue Pharma L.P., et al.*, Case No. 17-op-45004 (N.D. Ohio) and *The County of Summit, Ohio, et al. v. Purdue Pharma L.P., et al.*, Case No. 18-op-45090 (N.D. Ohio) (“Track One Cases”). I understand that these two cases assert claims on behalf of Cuyahoga and Summit Counties in Ohio against a number of pharmaceutical manufacturers, distributors, and retail pharmacies, including Walmart.
- B. I have been asked to offer my opinions and provide expert testimony concerning Walmart’s policies and procedures as a DEA registrant to distribute controlled substances, in particular Schedule II opioids, during the time period of January 1, 2006 to April 25, 2018 (the “relevant time period”).
- C. The facts and opinions expressed in my report are based on my experience, review of publicly available information, review of documents produced in discovery, and review of depositions conducted in this matter.

D. Summary of Opinions

1. It is my opinion that Walmart maintained sufficient and effective controls to guard against the diversion of controlled substances into other than legitimate medical, scientific or industrial channels.
2. It is my opinion that Walmart’s suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA.
3. It is my opinion that Walmart enhanced and upgraded its SOM program over time in furtherance of its regulatory obligations.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

4. It is my opinion that Walmart appropriately leveraged information and data available to it as a self-distributor to conduct due diligence and to know its customers (its own pharmacies) in its evaluation of orders placed for controlled substances.
5. It is my opinion that Walmart utilized the fact that it was a self-distributor to also appropriately leverage personnel (*e.g.*, pharmacists/field leadership) to assist in the due diligence process.
6. It is my opinion that a sufficient suspicious order monitoring system must be tailored to each registrant's business and that the approaches Plaintiffs' counsel asked Mr. McCann to apply to flag orders in his expert report submitted in this case are inappropriate.
7. I hold the opinions I express in this report to a reasonable degree of professional certainty.

II. Qualifications and Experience

- A. As detailed in my Curriculum Vitae, attached as Appendix A, I hold the following degrees:
 1. In 1993, I received a bachelor's degree in Sociology from Providence College with honors (*Magna Cum Laude*).
 2. In 1996, I received my Juris Doctorate from Seton Hall University, School of Law, with honors (*Magna Cum Laude*).
- B. Between September 1996 and February 2012, I held various government positions as described in my Curriculum Vitae.
- C. In February 2012, I was hired as a Senior Attorney at the U.S. Drug Enforcement Administration (DEA), Office of Chief Counsel, Diversion and Regulatory Litigation

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

Section (CCD). While in this position, my duties and responsibilities included the following, among other responsibilities:

1. Supervising administrative investigations of DEA registrants to determine compliance with the Controlled Substances Act (CSA) and registrants' implementation of regulations, including gathering and reviewing evidence and conducting witness interviews.
2. Evaluating the merits of investigated matters to determine the appropriate administrative action, if any, to be taken, including whether to file actions to revoke or deny registrations to handle controlled substances.
3. Drafting show-cause and immediate suspension orders.
4. Litigating administrative hearings against DEA registrants.
5. Negotiating settlements with DEA registrants.

D. On or around January 2016, I was detailed to the Office of the Deputy Administrator where I began working on a project to review, evaluate and update DEA policies and procedures. I still retained responsibility for some CCD matters during this time.

E. On or around May 2016, DEA created the Office of Compliance at which time I began working primarily in that office, where I remained until I left DEA in June 2018. My responsibilities included, but were not limited to, reviewing, evaluating, and updating DEA policies and procedures.

F. In June 2018, I joined Guidepost Solutions as a Managing Director.

G. The opinions presented in this report are based on my experience and education as well as my review of public records and documents and testimony produced in this litigation. I have not used or relied upon any confidential DEA or DOJ information in this report. The

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

list of specific materials that I considered in forming my opinions in this report is attached as Appendix B.¹

H. Guidepost Solutions is being compensated at my standard billing rate of \$650 per hour.

My compensation in this matter is in no way contingent or based on the content of my opinion or the outcome of this or any other matter.

I. I reserve the right to update my analysis and opinions based on any additional information I may receive.

III. Factual Background

A. Walmart

1. Walmart owns and operates retail stores throughout the United States, including in the Track One jurisdictions. From groceries and electronics to sporting goods and crafts, Walmart seeks to offer “everyday low prices” and the convenience of “one-stop shopping” to its customers.²
2. Certain Walmart stores contain pharmacies within the store for the customers’ convenience. Walmart pharmacists dispense many types of prescription and non-prescription medications, including controlled substances.
3. During the relevant time period, Walmart self-distributed pharmaceuticals to Walmart pharmacies from Walmart pharmacy distribution centers.
 - a. During the time period when Walmart self-distributed Schedule II controlled substances (from 2002 until April 2018), all Schedule II controlled substances were

¹ It is my understanding that my report is being served on the DOJ to allow DOJ the opportunity to request that certain portions of my report be redacted.

² See <https://corporate.walmart.com/our-story/our-business>.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

distributed from only one Walmart pharmacy distribution center—Distribution Center No. 6045 (“DC 6045”) located in Arkansas.

- b. Walmart self-distributed Schedule III-V controlled substances to its own pharmacies in the Track One jurisdictions from DC 6046 (located in Maryland) and DC 6028 (located in Indiana).
 - c. During the time when Walmart self-distributed controlled substances, Walmart pharmacies were able to order items not stocked in the Walmart distribution centers from McKesson. Due to power of attorney requirements, if the item was a Schedule II controlled substance, the pharmacy could not order it directly through McKesson, but rather had to place the order through Walmart’s DC 6045.³
- 4. Because Walmart’s pharmacies were located within Walmart retail stores, Walmart’s compliance and pharmacy distribution operations had access to pharmacy-level information, such as: prescriber information, the ratio of controlled substances to non-controlled substances dispensed from (and purchased by) the pharmacies, and the ratio of controlled substances paid for in cash within the pharmacies.
 - 5. Walmart was able to appropriately leverage this pharmacy-level information when executing its Suspicious Order Monitoring (SOM) program.
 - 6. Between 2015 until Walmart ceased self-distributing controlled substances in approximately April 2018, Walmart specifically recorded the percentage of controlled substances to non-controlled substances dispensed at the pharmacies in the Track One jurisdictions for use in its SOM program. During this time period, the ratio of controlled substances to non-controlled substances for these pharmacies in the Track

³ See, e.g., M. Johnson Dep. Transcript (230:7-231:1; 241:20-242:8).

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

One jurisdictions ranged between approximately 4% and approximately 15%.⁴ Based on my experience, these control to non-control ratios are well within the bounds of what I would expect for a pharmacy exercising appropriate controls against diversion.

7. As a self-distributor of controlled substances, Walmart only distributed to its own pharmacies and did not distribute controlled substances to any internet pharmacies or pain clinics, let alone the internet pharmacies and pill mills known to have diverted controlled substances for illegitimate purposes.

B. Walmart's Suspicious Order Monitoring (SOM) Program

1. Walmart encouraged continuous improvement of processes and procedures within the company, including with its SOM program.
2. Walmart's SOM program evolved over time and operated in the manner described in more detail below.
3. Walmart employed various systems to detect and report suspicious orders. These systems were both manual and automated.

DC Associate Review

4. Throughout the relevant time period, tenured associates, who had typically worked in Walmart's pharmacy distribution centers for several years, monitored controlled substance orders as they were being processed and filled.⁵
5. Pursuant to this process, when orders were identified for review, they were held during the review process and not shipped to the pharmacy. Managers in Walmart's pharmacy distribution centers followed up on these orders by reviewing prior order history, speaking with pharmacists, and escalating issues to field leadership as needed to

⁴ See, e.g., WMT_MDL_000058588.

⁵ See, e.g., S. Hiland-Rule 30(b)(6) Dep. Transcript (45:10-46:2; 209:13-212:9; 226:24-227:16).

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

investigate orders and/or resolve concerns.⁶ This process was separate from the compilation and review of the Controlled Drug Stock Exception Reports (“SD405”) and other processes, described below.

SD405 Reports

6. Walmart’s SD405 report was issued separately for each pharmacy distribution center on a monthly basis, and identified controlled substances shipped to Walmart’s pharmacies during the prior month broken down by item (SD405-1 report) and by store (SD405-2 report). The SD405 report ranks the top stores by percentage of the stores’ total monthly pharmacy shipments for each controlled substance.⁷ The report includes the following information:
 - a. Walmart pharmacy store number, location and DEA registration number;
 - b. Item number and description;
 - c. Quantity of item (controlled substances) distributed to the pharmacy for the month (Quantity Picked);
 - d. Quantity of total controlled and non-controlled substances distributed to the pharmacy for the month (Store Total Picked);
 - e. Calculation of the percentage of the particular controlled substance (item) listed to the total amount of controlled and non-controlled substances distributed to the pharmacy for the month (PCT of Total).
7. From as early as 1994 until 2010, associates in Walmart’s pharmacy distribution centers reviewed the SD405 reports, followed up on outlier stores flagged using the

⁶ See, e.g., *Id.*

⁷ See, e.g., WMT_MDL_000046008; WMT_MDL_000011106.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- SD405 report by speaking with pharmacists, and escalated issues to field leadership and other Walmart personnel as needed to investigate orders and/or resolve concerns.⁸
8. Beginning in approximately 2004 until at least August 2010, employees in DC 6045, based on their review of SD405 reports, faxed monthly reports to the Little Rock DEA office. These reports identified to DEA potential outlier pharmacy orders that were flagged when compared to other orders placed by other Walmart pharmacies for the same product.⁹
9. From approximately 2010 until 2015, employees in Walmart’s pharmacy distribution centers reviewed the SD405 reports and internally circulated reports listing all stores/items above 3.99% (referred to as “4% reports”) for further review and follow-up as needed.¹⁰
10. Specifically, these 4% reports listed any controlled substance ordered by any store that was over 3.99% of the store’s total orders for a given month. The 4% reports were internally circulated for further review and investigation.¹¹

Reddwerks Order Alerts

11. From approximately 2011 until 2015, Walmart implemented order alerts in Reddwerks (Walmart’s order fulfillment system) that flagged orders for controlled substances of 50 bottles or more and orders for amounts 30% higher than a rolling 4-week average for that store/item combination.¹²

⁸ See, e.g., S. Hiland-Rule 30(b)(6) Dep. Transcript (169:22-170:16; 221:6-10).

⁹ See, e.g., WMT_MDL_000046008.

¹⁰ See, e.g., WMT_MDL_000011106 (PM 21-402).

¹¹ See, e.g., WMT_MDL_000009437.

¹² See, e.g., WMT_MDL_000009224.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

12. The flagged orders were held and reviewed in the pharmacy distribution center prior to being shipped.

20-Bottle Limit and Report

13. In July 2012, Walmart implemented a hard limit of 20 bottles (per week/per store) for shipments of Oxycodone 30 mg, and internally circulated a report listing orders for Schedule II controlled substances of more than 20 bottles for further review and follow-up as needed.¹³
14. Depending on the order, this process may have involved personnel at the pharmacy distribution center as well as the Asset Protection team (located at Walmart's Home Office) and the Practice Compliance team.

Enhanced Reddwerks Thresholds

15. In 2014, Walmart memorialized certain SOM program policies and procedures already in existence and enhanced other policies and procedures, including but not limited to the following:¹⁴
- a. Defined order of interest and suspicious order;
 - b. Delineated roles and responsibilities of Walmart personnel at various stages in the SOM program process;
 - c. Created a dedicated logistics compliance team to review and evaluate orders of interest;
 - d. Provided guidance on the evaluation of orders of interest;
 - e. Required certain documentation to accompany the due diligence efforts;
 - f. Implemented oversight activities over the SOM program.

¹³ See, e.g., WMT_MDL_000057248; WMT_MDL_000009427; WMT_MDL_000009423.

¹⁴ See, e.g., WMT_MDL_000011107.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

16. From approximately 2015 through November 2017, Walmart implemented enhanced thresholds in Reddwerks that were item and store specific and continued the tiered review process (involving teams from Walmart’s Health & Wellness Logistics and Practice Compliance) for flagged orders placed by its pharmacies.
17. According to Walmart’s policies and procedures, the tiered review process included a review of information pertinent to each order, including the “store profile” of the pharmacy that placed the order, as well as interaction with the pharmacy personnel and the market director (who supervised the pharmacy), if needed.
18. The store profile included basic information about the pharmacy, as well as the controlled to non-controlled substance percentages for each store, which was updated on a quarterly basis. If an order was escalated to the Practice Compliance team, additional information concerning the order was reviewed. The tiered review process was documented in an internal Walmart system known as Archer, which could generate reports containing details of what occurred during the review.¹⁵
19. Orders were held at the pharmacy distribution center and not shipped until the review process was complete and the order was deemed appropriate. Walmart policies and procedures required that any order deemed suspicious be reported to DEA.¹⁶

Buzzeo System

20. From November 2017 until approximately April 2018 when Walmart ceased distribution of controlled substances, Walmart used the Buzzeo SOM system to analyze orders from Walmart pharmacies and flag orders of interest, which were reviewed by Walmart’s Health & Wellness Practice Compliance personnel.

¹⁵ See, e.g., WMT MDL 000043808.

¹⁶ See, e.g., WMT MDL 000000963.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

21. During this time, the review of flagged orders took place entirely within the practice compliance team. To assist with this process, Walmart employed pharmacists to review orders of interest.
22. Based on its interpretation of the *Masters* decision issued in June 2017,¹⁷ Walmart reported to the DEA all orders of interest identified using the Buzzeo system prior to review of the orders to determine whether they were appropriate orders that could be shipped.¹⁸
23. Shortly after Walmart began reporting orders of interest in this manner, DEA contacted Walmart and asked that Walmart stop reporting orders of interest to DEA. Walmart requested that DEA confirm this guidance in writing and, in the interim, continued to report orders of interest in this manner until it ceased self-distribution of controlled substances in approximately April 2018.¹⁹
24. Similar to earlier processes, orders were held and not shipped until the review process was complete and the order was deemed appropriate.
25. The review process continued to be documented in the Archer database. The reports capable of being produced during this time included additional fields and information documenting the due diligence that was conducted.²⁰

¹⁷ In 2015, after DEA issued an Order to Show cause to revoke the DEA registration of Masters Pharmaceutical, Inc., the DEA Acting Administrator issued a Final Order revoking Masters' DEA registration. In 2017, the United States Court of Appeals for the D.C. Circuit upheld the Final Order of the Acting DEA Administrator regarding Masters Pharmaceutical, Inc.'s registration.

¹⁸ See, e.g., WMT_MDL_000055271.

¹⁹ See, e.g., WMT_MDL_000055279; S. Hiland-Rule 30(b)(6) Dep. Transcript (456:10-24).

²⁰ See, e.g., WMT_MDL_000043807.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

C. Walmart's Physical Security and Other Anti-Diversion Policies and Procedures

Physical Security

1. Walmart maintained physical security at the Walmart pharmacy distribution centers which included, but was not limited to, physical security, closed-captioned television cameras (CCTV), alarms and 24/7 alarm monitoring, limitations on employee access to areas which contained controlled substances, and other security measures to prevent the diversion of controlled substances in its pharmacy distribution centers.
2. In addition to limiting access to areas that contained controlled substances, Walmart maintained logs to track personnel movements in and out of the facility; conducted daily inventory checks to ensure every controlled substance item was accounted for; strategically placed CCTVs in its pharmacy distribution centers so that Walmart could monitor controlled substances from the moment they entered the facility to the time they left for the pharmacy; and asset protection personnel at the pharmacy distribution center who provided additional security.²¹

Theft and Loss

3. Walmart had policies and processes in place to detect theft or loss of controlled substances in Walmart pharmacy distribution centers and Walmart pharmacies; investigated the theft or loss; reported any significant theft or loss to DEA on a DEA Form 106; and took other appropriate measures as necessary.

In Transit Security

4. Walmart policies and procedures required that deliveries of controlled substances be made directly to the pharmacy (as opposed to the Walmart retail store). DC 6045 had

²¹ See, e.g., WMT_MDL_000000840; WMT_MDL_000000885.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

the capability to track each Schedule II controlled substance order from the distribution center to the pharmacy until the delivery was completed and all Schedule II orders required a signed Proof of Delivery (POD). Walmart's policies further required that a designated DC 6045 employee monitor each Schedule II order and contact the Walmart pharmacy if the POD was not signed within 24 hours of scheduled delivery in order to verify delivery.²²

Walmart Pharmacy Anti-Diversion Policies

5. Similar to Walmart pharmacy distribution centers, Walmart pharmacies are monitored with CCTV cameras and alarm systems. All controlled substances are stored in the Walmart pharmacy and access to the pharmacies is strictly limited to pharmacy personnel. Schedule II controlled substances are maintained in a separate, locked drawer and only Walmart pharmacists have the keys to the Schedule II drawers. Pharmacists are always required to keep the keys on their person.
6. Walmart also implemented the following policies regarding the filling of Schedule II controlled substance prescriptions: documentation of the Schedule II controlled substance prior to filling (use of logbook and electronic scanner); requirement that at least two pharmacy employees, including the pharmacist, are involved in the filling of a Schedule II controlled substance prescription; and guidance to pharmacy personnel regarding the identification and reporting of fraudulent prescriptions (*e.g.*, anomalies in the hard copy prescription or in patient behavior).²³

²² See, *e.g.*, WMT_MDL_000000828.

²³ See, *e.g.*, WMT_MDL_000043074; WMT_MDL_000055445.

D. Walmart's Interactions with DEA

Cyclic Investigations/Audits

1. During the relevant time period, DEA conducted a number of inspections and audits of Walmart's DC 6045, DC 6046, and DC 6028.
2. Based on my review of documents, it appears that these inspections and audits included reviews of Walmart's SOM program.²⁴
3. I understand that DEA witnesses have testified that if a registrant interacted with a DEA field office or agent, DEA not only expected that registrant to listen to the information it received from the field office or agent but agreed that it is reasonable for that registrant to rely on the information received from the field office or agent.²⁵
4. I am further aware that DEA witnesses have testified that if, during an inspection of a registrant's facilities, it perceived a deficiency DEA would affirmatively notify the registrant of that perceived deficiency.²⁶
5. It is my understanding based on the documents and testimony I have reviewed that DEA did not issue any Orders to Show Cause or Immediate Suspension Orders against any Walmart pharmacy distribution center.

DEA Diversion Priorities

6. I am aware from publicly available information, including press releases, news articles and other open source information that DEA has taken enforcement actions with regard to certain distributor registrants. In addition, I am generally aware of DEA's stated priorities during the specified time period.

²⁴ See, e.g., WMT MDL 000034284; WMT MDL 000053976.

²⁵ See, e.g., K. Wright Dep. Transcript, Vol. I (231:2-232:14); T. Prevoznik Dep. Transcript, Vol. II (460:17-461:21).

²⁶ See, e.g., T. Prevoznik Dep. Transcript, Vol. I (130:2-131:23).

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

7. Prior to 2010, DEA’s diversion priorities were focused on rogue or illegal internet pharmacies and illegal pain clinics or “pill mills,” because they were viewed as the source of most illegally diverted opioids.²⁷
8. Additionally, as confirmed in deposition testimony by DEA offered in this litigation, Mr. Rannazzisi testified in April 2014 that 99.5% of prescribers were not overprescribing and that these rogue pain clinics constituted 0.5% of all prescribers.²⁸
9. As I mentioned above, Walmart did not distribute opioids to any pill mills or pain clinics.

IV. Relevant Legal and Regulatory Scheme

- A. The mission of DEA’s Diversion Control Division “is to prevent, detect, and investigate the diversion of controlled pharmaceuticals and listed chemicals from legitimate sources while ensuring an adequate and uninterrupted supply for legitimate medical, commercial, and scientific needs.”²⁹
- B. Pursuant to 21 C.F.R. § 1301.71(a), “all registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.”
- C. 21 C.F.R. § 1301.71(b) allows for “substantial compliance” with the regulations “after evaluation of the overall security system and needs of the ... registrant.”
- D. 21 C.F.R. § 1301.74(b) requires that the registrant “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” “Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

²⁷ See, e.g., T. Prevoznik Dep. Transcript, Vol. II (469:23-471:9).

²⁸ See, e.g., J. Rannazzisi Dep. Transcript, Vol. I (191:18-193:9).

²⁹ See <https://www.dea.gov/diversion-control-division>.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

E. 21 C.F.R. § 1301.74(b) requires that any suspicious order be reported to DEA by the registrant “when discovered.”

F. 21 C.F.R. § 1301.72 describes certain physical security requirements for DEA registered locations.

V. Opinions Regarding Walmart’s Diversion Controls and Suspicious Order Monitoring Program

A. General

1. It is my opinion that Walmart maintained sufficient and effective controls to guard against the diversion of controlled substances into other than legitimate medical, scientific or industrial channels.
2. It is my opinion that Walmart’s suspicious order monitoring system was sufficient and effective to detect and report suspicious orders to DEA.
3. It is my opinion that Walmart enhanced and upgraded its SOM program over time in furtherance of its regulatory obligations.
4. It is my opinion that Walmart appropriately leveraged information and data available to it as a self-distributor to conduct due diligence and to know its customers (its own pharmacies) in its evaluation of orders placed for controlled substances.
5. It is my opinions that Walmart utilized the fact that it was a self-distributor to also appropriately leverage personnel (*e.g.*, pharmacists/field leadership) to assist in the due diligence process.

B. SOM Program Analysis – 2004 to 2010

1. It is my opinion that Walmart’s SOM program during this time period was sufficient and effective to guard against the diversion of controlled substances into other than legitimate medical, scientific or industrial channels.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

2. Further, it is my opinion that Walmart's SOM program during this time period was sufficient to detect and report suspicious orders to DEA.
3. My opinions are based on various components of Walmart's SOM program, including but not limited to the following:
 - a. When orders were flagged in the pharmacy distribution centers, they were held during the review process and not shipped to the pharmacy. These orders were subject to due diligence by tenured associates in Walmart's pharmacy distribution centers prior to shipping.
 - b. Pharmacy distribution center employees reviewed SD405 reports and conducted due diligence on stores flagged using the SD405 reports.
 - c. From 2004 until 2010, employees in DC 6045 faxed monthly reports to the Little Rock DEA office that identified potential outlier pharmacy orders that were flagged when compared to other orders placed by other Walmart pharmacies for the same product.
4. I am aware that DEA audited and inspected Walmart pharmacy distribution centers on numerous occasions during this time period and did not bring any enforcement actions against Walmart for any non-compliance with the CSA or its implementation of regulations regarding suspicious order monitoring.

C. SOM Program Analysis – 2010 to 2015

1. Based on my review of documents, between approximately 2010 and 2015, Walmart enhanced and improved its SOM program in numerous ways, as described further below.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- a. Walmart monitored controlled substances ordered by its pharmacies that exceeded 3.99% of all a store's total orders (both controlled and non-controlled) for a given month.
 - b. Walmart leveraged its electronic order fulfillment system to implement order alerts that flagged orders for controlled substances of 50 bottles or more and orders for amounts 30% higher than a rolling 4-week average for each store/item combination. These orders were held and reviewed in the pharmacy distribution center prior to being shipped.
 - c. Beginning in approximately July 2012 Walmart implemented a hard limit of 20 bottles (per week/per store) for shipments of Oxycodone 30 mg.
 - d. Also in 2012, Walmart created a report identifying all orders for Schedule II controlled substances of more than 20 bottles for further review and follow-up as needed. Depending on the order, the process may have involved personnel at the pharmacy distribution center as well as the Asset Protection team (located at Walmart's Home Office) and the Practice Compliance team.
 - e. In 2014, Walmart memorialized certain SOM program policies and procedures already in existence and enhanced other policies and procedures.
2. It is my opinion that Walmart's SOM program during this time period was sufficient and effective to guard against the diversion of controlled substances into other than legitimate medical, scientific or industrial channels.
 3. It is my opinion that Walmart's SOM program during this time period was sufficient to detect and report suspicious orders to DEA.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

4. Based upon the documents I reviewed, I saw evidence that Walmart implemented and followed the policies and procedures of its SOM program that were in place during this time period.
5. It is my opinion that Walmart effectively leveraged the information, data, and personnel available to it in furtherance of its SOM program.

D. SOM Program Analysis – 2015 to 2018

1. Based on my review of documents, between approximately 2015 and 2018, Walmart continued to enhance and improve its SOM program in numerous ways, as described further below.
 - a. From approximately 2015 through November 2017, Walmart implemented enhanced thresholds in Reddwerks and a tiered review process (involving teams from Walmart's Health & Wellness Logistics and Practice Compliance divisions) for flagged orders placed by its pharmacies.
 - b. Walmart utilized pharmacy data within its own system to assist in the review of flagged orders.
 - c. In November 2017, Walmart further enhanced its SOM program when it switched to the Buzzeo system to analyze orders from Walmart pharmacies and flag orders of interest.
 - d. During this time from November 2017 until approximately April 2018 when Walmart ceased distribution of controlled substances, all orders of interest identified using the Buzzeo system were reported to DEA.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- e. For both the Reddwerks and Buzzeo systems, the due diligence conducted was documented in an internal Walmart system known as Archer, which could produce reports containing details of what occurred during the review.
 - f. For both the Reddwerks and Buzzeo systems, orders were held and not shipped until the review process was complete and the order was deemed appropriate. Walmart policies and procedures required that any order deemed suspicious be reported to DEA.
2. It is my opinion that Walmart's SOM program during this time period was sufficient and effective to guard against the diversion of controlled substances into other than legitimate medical, scientific or industrial channels.
 3. It is my opinion that Walmart's SOM program during this time period was sufficient to detect and report suspicious orders to DEA.
 4. Based on the documents I reviewed, I saw evidence that Walmart sought to enhance its SOM program during this period, and that some of the enhancement implemented had a direct relationship to problems or issues occurring in the pharmaceutical industry.
 5. Based upon the documents I reviewed, I saw evidence that Walmart did in fact implement and follow the policies and procedures of its SOM program that were in place during this time period.
 6. Based on the documents I reviewed, I saw evidence that Walmart documented the processes and efforts supporting its due diligence efforts and the manner in which it implemented its policies and procedures.
 7. It is my opinion that Walmart appropriately leveraged the information, data and personnel available to it in furtherance of its SOM program.

E. Walmart's Physical Security and Anti-Diversion Policies

1. Based on my review of documents and testimony provided in this litigation, it is my opinion that Walmart's physical security controls and other anti-diversion policies and procedures in its pharmacy distribution centers and pharmacies substantially supported Walmart's effective system against the diversion of controlled substances into other than legitimate medical, scientific or industrial channels.
2. My opinion in this regard is based in part on the following observations:
 - a. Walmart pharmacy distribution centers maintained a considerable physical security system as described in detail above.
 - b. Employees at Walmart's pharmacy distribution centers were required to complete a daily inventory of all items, including controlled substances.
 - c. Employees at Walmart's pharmacy distribution centers were required to contact the Walmart pharmacy if the proof of delivery was not signed within 24-hours of scheduled delivery of a Schedule II controlled substance.
 - d. Walmart's pharmacies also employed a number of physical security protocols. For example, pharmacy policies and procedures restricted access to the pharmacy area and to Schedule II controlled substances.
 - e. Employees in Walmart pharmacies were given significant written guidance to assist with the identification and report of fraudulent controlled substance prescriptions.

VI. Expert Report of Craig J. McCann, Ph.D., CFA

- A. I have been asked to render an opinion regarding Mr. McCann's analysis of transactional data and the approaches he applied to arrive at his conclusions.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

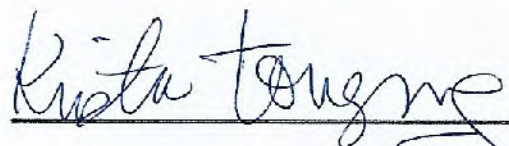
- B. Mr. McCann broadly states that he “implemented various approaches to identify transactions meeting specified criteria”³⁰ using ARCOS data from 2006 to 2014 produced by the DEA and supplemented with transactional data produced by Defendants (“Combined Transactional Data”). Mr. McCann’s “approaches” are in fact methods by which to calculate “thresholds.”
- C. Mr. McCann calculates the various thresholds and applies them to the Combined Transactional Data. He then, at the direction of Plaintiffs’ Counsel, assumes that “the Distributor did not effectively investigate the flagged transactions and so every subsequent transaction . . . is also flagged because the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction.”³¹
- D. In my opinion, based on the documents and testimony I have reviewed in this matter, this assumption and approach is incorrect, especially as applied to Walmart. As detailed above in my discussion of Walmart’s SOM program, Walmart employed various methods to detect and investigate flagged transactions. Mr. McCann made no effort to consider the specifics of Walmart’s SOM program in his threshold analyses. Further, I am aware that DEA witnesses testified that distributor registrants can and should develop methods to detect and report suspicious orders that are unique to its business model and that evolve over time. I am aware that DEA witnesses have testified that DEA considers the development of SOM programs as business decisions of each distributor registrant.

³⁰ C. McCann Report (March 25, 2019) at pp. 56-76. The threshold analyses used by Mr. McCann are as follows: Maximum Monthly, Trailing Six-month Threshold; Twice Trailing Twelve-month Average Pharmacy Dosage Units; Three Times Trailing Twelve-month Average Pharmacy Dosage Units; Maximum 8,000 Dosage Units Monthly; and Maximum Daily Dosage Units.

³¹ C. McCann Report (March 25, 2019) at pp. 56-57.

HIGHLY CONFIDENTIAL – SUBJECT TO PROTECTIVE ORDER

- E. Mr. McCann's transactional analysis does not consider the fact that Walmart self-distributed products to only its own pharmacies nor does he consider the various policies and procedures Walmart had in place to guard against diversion. Furthermore, Mr. McCann's application of his threshold analysis does not evolve over time. Instead it applies a static threshold over a period of eight years and assumes every controlled substance shipped over that threshold should have been flagged because it was not reviewed or investigated.
- F. Mr. McCann also appears to inappropriately apply a "one size fits all" approach to his threshold calculations. For example, he applies a Cardinal Health "Maximum Daily Dosage Units" threshold to Defendants' transactions.³² I am aware from the documents and testimony reviewed in this case that Cardinal Health is fundamentally different from Walmart in that Cardinal Health distributes controlled substances to independent retail pharmacies, among other entities, while Walmart only self-distributed controlled substances to its own pharmacies during the relevant time period.
- G. Given the flaws identified above, it is my opinion that Mr. McCann's application of the approaches he identifies to Walmart's transactions is inappropriate and unreliable as it ignores relevant documentary and testimonial evidence.



Krista Tongring

³² C. McCann Report (March 25, 2019) at pp. 72-76.

APPENDIX A

KRISTA TONGRING
Guidepost Solutions LLC
1130 Connecticut Avenue NW Suite 520
Washington, DC 20036
(202)780-2945 (O)
(202)450-8081 (C)

CURRENT POSITION

June 2018 **Managing Director**
to Present Guidepost Solutions LLC

PAST EXPERIENCE

January 2016 **Acting Section Chief**
to June 2018 Office of Compliance, Policy
Administration Section United States
Drug Enforcement Administration
United States Department of Justice
Arlington, Virginia

- Execute the functions of the Acting Section Chief of the Policy Administration Section in its mission to coordinate with policy stakeholders to ensure that DEA policy is easily understood and internally consistent, relevant to current DEA's mission, easily accessible in a central location, properly archived in accordance with federal law, and consistent with current DOJ policy and federal law.
- Assess DEA policy to identify potential areas of weakness or risk to the agency and collaborate with stakeholders to develop action plans to mitigate the risk.
- Coordinate with the Chief Compliance Officer and other senior DEA officials to establish long term program goals of the Policy Administration Section – develop and implement processes and plans to meet those goals.
- Develop strategic plan to facilitate DEA policy administration process through which all new or revised DEA policy will be reviewed and approved – develop written administrative guidelines, establish a regular policy review process, and oversee the creation of an electronic workflow and a centralized policy website.
- Establish and maintain relationships with DEA Division/Office Heads and their representatives in order to further DEA policy improvements and Policy Administration Section initiatives.
- Participate in the identification budget requirements for Policy Administration Section initiatives and coordinate with the Chief Compliance Officer and other DEA staff to ensure proper execution of initiatives.

February 2012 to January 2016 **Senior Attorney (GS-15)**
Diversion & Regulatory Litigation Section
United States Drug Enforcement Administration
United States Department of Justice
Arlington, Virginia

- Supervised administrative investigations of DEA registrants to determine compliance with the CSA and its implementing regulations.
- Evaluated the merits of investigated matters to determine whether administrative actions should be filed to revoke or deny registrations to handle controlled substances, coordinated with DEA investigators, gathered and reviewed evidence, conducted witness interviews, and prepared litigation recommendations.
- Drafted show-cause and immediate suspension orders and litigated administrative hearings, developed trial strategy, researched and wrote motions, presented witnesses at hearing, and prepared post-trial briefs.
- Investigated, charged, and litigated the administrative case against Masters Pharmaceuticals, Inc.
- Negotiated complex, multi-district settlements with DEA registrants.

January 2010 to February 2012 **Associate Counsel**
International Organized Crime Intelligence and
Operations Center (IOC-2)
United States Department of Justice
Fairfax, Virginia

- Served as IOC-2 representative in high-level meetings with members of federal law enforcement and intelligence agencies, as well as international, state, and local law enforcement counterparts, regarding all aspects of IOC-2, including discussions on international organized crime, racketeering, the Bank Secrecy Act (BSA), money laundering, virtual currency, and other investigations of financial crime.
- Participated in nomination and selection process of international organized crime groups to the Top International Criminal Organization Target (TICOT) list.
- Monitored and coordinated national and international prosecutions of TICOT list targets, including meeting with U.S. and international law enforcement and intelligence representatives.
- Drafted and reviewed Memoranda of Understanding between the IOC-2 and member law enforcement agencies.
- Executed Mutual Legal Assistance requests pertaining to foreign international organized crime investigations and prosecutions.

January 2006 **Trial Attorney**
to February 2012 United States Department of Justice - Criminal Division
Organized Crime and Gang Section
(formerly Organized Crime and
Racketeering Section) Washington, DC

- Led criminal investigations and prosecutions into violations of racketeering, BSA, money laundering, and other financial crimes.
- Drafted prosecution memoranda, indictments, and pleadings in furtherance of criminal prosecutions.
- Presented witnesses and indictments to the grand jury, prosecuted jury trials, and negotiated complex plea agreements.
- Participated substantially in the creation and implementation of a complex financial investigation seminar designed to train inexperienced agents, investigators, and prosecutors how to properly investigate and successfully prosecute complex criminal financial cases using racketeering, BSA, money laundering, and associated criminal forfeiture statutes. Served as a facilitator and instructor for this seminar.
- Conducted international training in association with the U.S. Department of Justice, Criminal Division, Overseas Prosecutorial Development, Assistance and Training Office.

September 1998 to January 2006 **Trial Attorney**
United States Department of Justice - Tax Division
Southern Criminal Enforcement Section

- Investigated and prosecuted complex tax, BSA, money laundering, and other tax-related and financial crimes, including criminal asset forfeiture, utilizing investigative tools such as undercover investigations, search warrants, electronic surveillance, and the development of cooperating witnesses.
- Drafted prosecution memoranda, indictments, pleadings, and other documentation for complex tax, money laundering, and other tax-related and financial crimes.
- Supervised ongoing investigations, presented witnesses and indictments to the grand jury, prosecuted jury trials, and negotiated plea agreements.

August 1997 to August 1998 **Judicial Law Clerk**
Honorable Joel B. Rosen, Magistrate Judge
(retired) United States District Court,
District of New Jersey Camden, New Jersey

August 1996 to August 1997 **Judicial Law Clerk**
Honorable Thomas F. Shebell, Jr., Presiding
Judge (retired) New Jersey Superior Court,
Appellate Division
Red Bank, New Jersey

AWARDS

Tax Division Outstanding Attorney Award - 2000, 2004
Tax Division Special Act or Service Award - 2005
Honorary IRS-CI Special Agent - 2005
Superior Performance Award - 2007, 2009
Special Achievement Award – 2010
Performance Award – 2016, 2015, 2014, 2012
Assistant Attorney General's Award
for Outstanding Trial Advocacy -
2008

EDUCATION

Seton Hall University School of Law,
Newark, N.J. J.D., June 1996, *Magna Cum Laude*

Providence College, Providence, R.I.
B.A., Sociology, May 1993, *Magna Cum Laude*

APPENDIX B

MATERIALS CONSIDERED

Deposition Materials

Transcript and Exhibits from Deposition of Jeff Abernathy (November 15, 2018)
Transcript and Exhibits from Deposition of Chad Ducote (November 16, 2018)
Transcript and Exhibits from Deposition of Miranda Johnson (December 12, 2018)
Transcript and Exhibits from Deposition of Ramona Sullins (January 4, 2019)
Transcript and Exhibits from Deposition of George Chapman (January 9, 2019)
Transcript and Exhibits from Deposition of Roxy Reed (January 10, 2019)
Transcript and Exhibits from Deposition of Debbie Hodges (January 11, 2019)
Transcript and Exhibits from Deposition of Greg Beam (January 15, 2019)
Transcript and Exhibits from Deposition of Kristy Spruell (January 16, 2019)
Transcript and Exhibits from Deposition of Walmart Rule 30(b)(6) (January 22, 2019)
Transcript from Deposition of Kyle Wright (February 28, 2019; March 4, 2019)
Transcript from Deposition of Keith Martin (April 4, 2019)
Transcript from Deposition of Thomas Prevoznik (April 17-18, 2019)
Transcript from Deposition of Joseph Rannazzisi (April 26, 2019)

Expert Reports and Materials

Craig McCann Report and Materials (3/25/2019); First Supplemental Report (4/3/2019); Original Files of Appendix; Supplemental Appendix F
Stephen Schondelmeyer Report and Materials (4/15/2019)

Additional Documents Produced In This Litigation

WMT_MDL_000000828-0832	WMT_MDL_000000840-0842	WMT_MDL_000000885-0888
WMT_MDL_000005598-5601	WMT_MDL_000005602-5606	WMT_MDL_000005607-5610
WMT_MDL_000008291	WMT_MDL_000008653-8655	WMT_MDL_000011641-1643
WMT_MDL_000012073-2074	WMT_MDL_000018827-8829	WMT_MDL_000034284
WMT_MDL_000043053-3061	WMT_MDL_000043074-3079	WMT_MDL_000043177-3185
WMT_MDL_000043807	WMT_MDL_000043808	WMT_MDL_000044441-4499

WMT_MDL_000053942-3955	WMT_MDL_000053976-4000	WMT_MDL_000055271-5276
WMT_MDL_000055279-5280	WMT_MDL_000055291	WMT_MDL_000055292
WMT_MDL_000055293-5296	WMT_MDL_000055297-5304	WMT_MDL_000055445-5450
WMT_MDL_000057248-7250	WMT_MDL_000057252-7253	WMT_MDL_000057255
WMT_MDL_000057262	WMT_MDL_000057263	WMT_MDL_000058588

Written Discovery

Walmart's Third Amended and Supplemental Interrogatory Responses

Walmart's Responses to Plaintiffs' (First) Combined Discovery Requests

Pleadings

The County of Summit, Ohio, et al. v. Purdue Pharma, L.P., et al., Case No. 18-op-45090 (N.D. Ohio) (May 18, 2018)

Statutes & Regulations

21 C.F.R. §1301.71, et seq.

Publicly Available Information

<https://corporate.walmart.com/our-story/our-business>

<https://www.cnn.com/2012/02/06/us/florida-dea-pharmacies/index.html>

Masters Pharmaceutical, Inc. v. Drug Enforcement Administration, 861 F.3d 206 (D.C. Cir. 2017)

In re Masters Pharmaceutical, Inc., 80 Fed. Reg. 55,418 (Drug Enf't Admin. Sept. 15, 2015)

<https://www.dea.gov/press-releases/2018/08/16/justice-department-dea-propose-significant-opioid-manufacturing-reduction>

<https://www.dea.gov/diversion-control-division> (mission)

<https://www.dea.gov/archive-press-releases> (press releases from the Miami Field Division between 2005 and 2010 relating to opioid cases)

DEA Press Release, DEA Serves Suspension Order on Walgreens Distribution Center in Jupiter, Florida (Sept. 14, 2012), *available at* <https://www.dea.gov/press-releases/2012/09/14/deaserves-suspension-order-walgreens-distribution-center-jupiter-florida>

SUPPLEMENT TO KRISTA TONGRING'S EXPERT REPORT DATED 5/10/2019

LIST OF PUBLICATIONS

“A Modern Curse: Fentanyl and FinCrime – A FINTRAIL Solutions thought piece,” with M. Redhead, *FINTRAIL Solutions, LLC* (Feb. 2019).